

Article - Health - General

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§17–210.

(a) The Secretary may deny a license to any applicant or suspend, revoke, or limit a license or the authority to offer or perform any class of service, complexity of testing, or tests that the license sets forth, if the medical laboratory or its director or other personnel fail to meet the standards and requirements under this subtitle and in regulations adopted pursuant to this subtitle.

(b) (1) If the Secretary finds that a laboratory issued a license under this subtitle no longer meets the standards and requirements under this subtitle and in regulations adopted pursuant to this subtitle, the Secretary may impose a directed plan of correction or limit the testing authorized by the license instead of suspending or revoking a license.

(2) (i) If the Secretary finds that a medical laboratory provided erroneous or questionable test results that pose a threat to the health and safety of patients, the Secretary may order the laboratory to:

1. Notify the physicians or other individuals who ordered the tests of the erroneous or questionable test results; and

2. Take any additional measures necessary to reduce or eliminate the threat to the health and safety of patients, including the notification of patients and the offering of retests.

(ii) A medical laboratory that fails to comply with an order issued by the Secretary under subparagraph (i) of this paragraph is subject to a civil penalty of up to \$1,000 for each day of noncompliance after the deadline for compliance stated in the Secretary's order, not to exceed a maximum penalty of \$50,000, instead of or in addition to any other sanction imposed under this section.

(c) Except as otherwise provided in the Administrative Procedure Act, before the Secretary denies, suspends or revokes a license, or imposes a civil penalty under this section, the Secretary shall give the applicant or licensee notice and an opportunity for a hearing.

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